and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989]

§ 5.53 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, declare as complete or incomplete, or revoke product development protocols for medical devices submitted under section 515(f) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

(b)(1) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, or withdraw approval of applications for premarket approval for medical devices submitted under sections 515 and 520(l) of the act:

(i) The Director and Deputy Director, CDRH, and the Director, Deputy Director, and Associate Director, Office of Device Evaluation, CDRH.

(ii) The Director and Deputy Director, CBER, and the Director and Deputy Director, Office of Biological Product Review, CBER.

(2) For medical devices assigned to their respective division, the Division Directors, Office of Device Evaluation, CDRH, are authorized to approve, disapprove, or withdraw approval of supplemental premarket applications.

(c) The Director and Deputy Director, CDRH, for medical devices assigned to their organization, are authorized to issue notices to announce the approval, disapproval, or withdrawal of approval of a device, and to make publicly available a detailed summary of the information on which the decision was based, under sections 515 (d), (e), and (g) and 520(h)(1) of the act.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 49 FR 21708, May 23, 1984; 50 FR 9424, Mar. 8, 1985; 54 FR 8317, Feb. 28, 1989]

§ 5.54 Determinations that medical devices present unreasonable risk of substantial harm.

The following officials, for medical devices assigned to their respective organizations, are authorized to determine that medical devices present an unreasonable risk of substantial harm to the public health, and to order adequate notification thereof, under section 518(a) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.

(c) The Director and Deputy Director, Center for Drug Evaluation and Research (CDER), and the Director and Deputy Director, Office of Compliance, CDER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 57 FR 40316, Sept. 3, 1992]

§ 5.55 Orders to repair or replace, or make refunds for, medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to order repair or replacement of, or refund for, medical devices under section 518 (b) and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Director, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Director, Office of Compliance and Surveillance, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Compliance, CBER.